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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,361	06/20/2003	Jean-Marie Andrieu	1187-R-02	7112
35811	7590	02/11/2004		EXAMINER LE, EMILY M
IP DEPARTMENT OF PIPER RUDNICK LLP 3400 TWO LOGAN SQUARE 18TH AND ARCH STREETS PHILADELPHIA, PA 19103			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/600,361	ANDRIEU ET AL.
	Examiner	Art Unit
	Emily Le	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 January 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-10,13,19,21-24 and 26-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4,5,11,12,14-18,20 and 25 is/are rejected.
- 7) Claim(s) 14-18 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I in Applicant's response to the restriction requirement, mailroom date of January 14, 2004 is acknowledged.

### **Status of Claims**

2. Claims 1-32 are pending in the application. Claims 3, 6-10, 13, 19, 21-24, 26-32 are withdrawn in view of Applicant's election. Claims 1-2, 4-5, 11-12, 14-18, 20, and 25 are currently under examination. To clarify, Group I is drawn to claims 1-2, 4-5, 11-12, 14-18, 20, **and 25**, not as stated in Applicant's response.

### ***Specification***

3. The attempt to incorporate subject matter into this application by reference to a list of publication is improper. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p). If Applicant wants the publication to be considered, Applicant is must enter the list on a PTO-1449 and provide a copy of each publication.

### ***Claim Objections***

4. Claims 14-18 are objected to because of the following informalities: It appears that there are two spelling errors: CB8+T and CTLE. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2, 14-18, 20, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not

have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

It is well known in the art that retroviral infections in general, and HIV infections in particular, are refractory to anti-viral therapies. The obstacles to therapy of HIV are well documented in the literature. These obstacles include: 1) the extensive genomic diversity and mutation rate associated with the HIV retrovirus, particularly with respect to the gene encoding the envelope protein; 2) the fact that the modes of viral transmission include both virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert manner, as well as via free virus transmission; 3) the existence of a latent form of the virus; 4) the ability of the virus to evade immune responses in the central nervous system due to the blood-brain barrier; and 5) the complexity and variation of the pathology of HIV infection in different individuals. The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to use the claimed invention with a reasonable expectation of success and without undue experimentation. Further, it is well known in the art that individuals infected with HIV produce neutralizing antibodies to the virus, yet these antibodies are not protective and do not prevent the infection from progressing to its lethal conclusion. Further, as taught by Fahey et al., clinical trials using a variety of immunologically based therapies have not yielded successful results in the treatment and/or prevention of HIV infection. Fahey et al. particularly discloses that monoclonal antibody therapies have not provided any clinical benefits and "it is not clear how adding

these additional antibodies would make a difference" (see page 3, second column, third full paragraph). The failure of all immune-system-boosting therapies for treating AIDS is further discussed by Fox. Thus, it is clear from the evidence of Fahey et al. and Fox, that the ability to treat and/or prevent HIV infection is highly unpredictable and has met with very little success. Applicants have not provided any convincing evidence that their anti HIV vaccine or composition is indeed useful **for an anti-HIV treatment** and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention with a reasonable expectation of success and without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- ((a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-5, and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Frank et al.

The claims are directed to a composition that comprises immature monocytes-derived dendritic cell pulsed with inactivated virus. The activity recited in the preamble of the claims do not lend any additional limitation to the claims,

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because the activity recited is an inherent property of any composition that comprises the same material or construct.

Frank et al. teaches a composition that comprises inactive SIV in immature dendritic cells (Page 2938). Therefore, Frank et al. anticipated the instantly claimed invention.

9. Claims 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Grovit-Ferbas et al.

Grovit-Ferbas et al. teaches a composition that comprises dendritic cells pulsed with inactivated HIV that substantially eradicate HIV-1 peripheral blood mononuclear cells (PBMC) (page 5803). Therefore, Grovit-Ferbas et al anticipated the instant invention.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 1, 2,11-12, 14-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frank et al.

The claims are directed to a composition that comprises dendritic cell pulsed with an inactivated human immunodeficiency virus (HIV). The claims are further limited with the addition of language that adds functionality to the claimed invention, such as: initiating an immune response against an immunodeficiency

virus, particularly HIV, and expanding the expression of virus-specific CD8+ T cells, which kills HIV infected cells, suppresses HIV type 1 replication, substantially eradicate HIV-1 in peripheral blood mononuclear cells, and increases HIV-specific cytotoxic T-lymphocyte activity of peripheral blood lymphocytes. As mentioned above, the activity recited in the preamble of the independent claim or further defined in dependent claims, do not lend any additional limitation to the claims, because the activity recited is an inherent property of any composition that comprises the same material or construct.

The relevance of Frank et al. is discussed above. Frank et al. does not teach the use of inactivated HIV virus. However, at the time of the claimed invention, it would have been obvious for one of ordinary skills to take the teaching of Frank et al. and substitute the inactivated SIV virus for an inactivated HIV virus because there exist a need for vaccines or composition that is directed to HIV treatment. One of ordinary skills in the art would have been motivated to take the teachings of Frank et al. and produce a composition that comprises dendritic cells pulsed with an inactivated human immunodeficiency virus as part of routine experimentation a reasonable expectation of success.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Emily Le

*James C. Housel*  
2/9/04